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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,993	02/18/2005	Ljubomir Antoncic	LI/G-33039A	3941

1095 7590 04/26/2007

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER
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FREISTEIN, ANDREW B

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/524,993

Applicant(s)

ANTONCIC ET AL.

Examiner

Andrew B. Freistein

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29, 31, 33-37 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29, 31, 33-37 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The amendment filed 2/20/2007 was entered. Claims 29, 31, 33-37 and 41-43 are pending. Claims 1-28, 30, 32, 38-40 and 44-50 were cancelled.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al., US 2004/0097568 A1. This rejection is maintained and made FINAL.

Applicant traverses the rejection by asserting that the reference is not prior art under 35 USC 102(e), because Applicants' filing date is January 30, 2003, June 12, 2003, and June 26, 2003, all of which are prior to the US filing date of the reference (July 29, 2003).

Examiner agrees that the priority documents have earlier filing dates than the reference. However, in order to claim benefit of the foreign priority documents, an English-language translation must be submitted with a certification of the accuracy of the translation. The Applicants have not provided English-language translations of the

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priority documents. See MPEP 35 USC 119(b)(3). Therefore, Reddy et al. is a prior art reference.

Applicant traverses the rejection arguing that 6 out of 10 values are at least 0.2 degrees 2-Theta different between the reference and the instant application. Examiner respectfully disagrees with Applicant. Applicant provides Table I:

Applicants	6.9	13.8	19.1	20.6	21.4	24.0	24.8	25.9	28.7	29.2
Form X										
Reddy Form III	7.2	13.9	19.3	20.7	21.6	24.1	24.9	26.1	28.9	29.5

This table allegedly shows that six peaks are greater than 0.2 degrees 2-Theta different from one another. However, this table fails to take into consideration the degree of difference in Form III of the prior art, which is 0.2 degrees 2-Theta. Form III is depicted below:

2- $\theta$ ( $^{\circ}$ )	Intensity (I/I <sub>0</sub> )	2- $\theta$ ( $^{\circ}$ )	Intensity (I/I <sub>0</sub> )
7.154	100	26.088	11.5
13.911	29.9	21.576	11.5
20.728	23.4	15.267	11.1
24.904	22.0	18.483	11.0
24.192	21.1	17.794	10.1
19.293	16.1	13.233	7.60
8.042	14.6	19.571	7.20
7.583	14.4	30.614	6.80
16.043	13.6		
17.194	13.3		
28.908	12.5		
29.474	11.9		

Applicant contends that the peaks are: 7.2, 13.9, 19.3, 20.7, 21.6, 24.1, 24.9, 26.1, 28.9 and 29.5. However, when adjusted by 0.2 degrees 2-Theta, the peaks range from: 7.0-7.4, 13.7-13.11, 19.1-19.5, 20.5-20.9, 21.4-21.8, 23.9-24.3, 24.7-25.1, 25.9-

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26.3, 28.7-29.1 and 29.3-29.7. Further, when the instant application is adjusted by 0.2 degrees 2-theta, the peaks are different. Comparing the instant application and the prior art should look like this:

Applicants Form X	6.7-7.1	13.6-14.0	18.9-19.3	20.4-20.8	21.2-21.6	23.8-24.2	24.6-25.0	25.7-26.1	28.5-28.9	29.0-29.4
Reddy Form III	7.0-7.4	13.7-14.1	19.1-19.5	20.5-20.9	21.4-21.8	23.9-24.3	24.7-25.1	25.9-26.3	28.7-29.1	29.3-29.7

As this table indicates, every single peak overlaps when the 0.2 degrees 2-Theta error is taken into account.

Applicant next argues the melting points of the prior art and the instant application is different and thus makes the instant claims patentable over the reference. The melting point range of Form X of the instant application is: 230-237°C and the prior art melting point of Form III is 254-260°C. Although these melting points are slightly different, this is not enough evidence to support a patentably distinct product.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As a result of the amendment filed 2/20/2007, this rejection is withdrawn.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

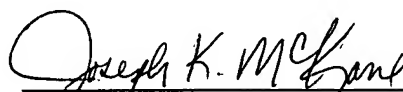
***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626



Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner, AU 1626  
Date: April 18, 2007